

DEPARTMENT OF HEALTH AND HUMAN SERVICES

DEC 04 1995

Our Reference Number: 90-0566

Mr. Matthew Klamrzynski
Abbott Laboratories
D49C, AP6C/2
Abbott Park, Buckley Road
and Waukegan Road
North Chicago, IL 60064

Dear Mr. Klamrzynski:

The Center for Biologics Evaluation and Research has completed its review of your request to supplement your product license application for Antibody to Hepatitis B Surface Antigen, to include the IMx® HBsAg and IMx® HBsAg Confirmatory enzyme immunoassays for the detection of Hepatitis B Surface Antigen (HBsAg) in human serum or plasma.

Based upon the review of information submitted in support of your request, the supplement has been found acceptable.

The expiration date of the IMx® HBsAg and IMx® HBsAg Confirmatory assays is twelve (12) months from the date of manufacture when stored at 2-8°C.

A copy of your labeling submission is enclosed. Please submit three (3) copies of final printed labeling at the time of use and include part II of the label transmittal form with completed implementation information.

In addition, advertising and promotional labeling in draft form should be submitted for review and approval prior to the initial publication of any advertisement and prior to the initial dissemination of any promotional labeling. All promotional claims must be consistent with and not contrary to approved labeling. No comparative promotional claim or claim of superiority over other similar products should be made unless data to support such claims are submitted to and approved by the Center for Biologics Evaluation and Research, Advertising and Promotional Labeling Staff, HFM-202.

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This information will be placed on file with your product license application for Antibody to Hepatitis B Surface Antigen (Mouse Monoclonal).

Sincerely yours,

Jay S. Epstein, M.D.
Director
Office of Blood Research and Review
Center for Biologics Evaluation
and Research

Enclosures